UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TINA M. COSH and LESTER A. COSH,
Plaintiffs,

-against-

ATRIUM MEDICAL CORPORATION,

Defendant.

1:18-cv-08335 (ALC)

OPINION & ORDER

ANDREW L. CARTER, JR., United States District Judge:

Plaintiffs Tina M. Cosh ("Mrs. Cosh") and Lester A. Cosh (collectively, the "Plaintiffs") bring this action against Defendant Atrium Medical Corporation ("Atrium"). In short, Plaintiffs allege that Mrs. Cosh sustained injuries as a result of the implantation of Atrium ProLite™ Mesh ("ProLite Mesh") during a hernia repair surgery in February of 2015. The Court previously dismissed the First Amended Complaint in its entirety. *Cosh v. Atrium Med. Corp.*, No. 1:18-cv-08335 (ALC), 2020 WL 583826, 2020 U.S. Dist. LEXIS 21008 (S.D.N.Y. Feb. 6, 2020) (*Cosh I*). The Court now considers a motion by Atrium to dismiss the Second Amended Complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Upon careful consideration, the Second Amended Complaint is **DISMISSED**.

BACKGROUND

The Court assumes the reader's familiarity with Plaintiffs' general allegations from *Cosh I*. However, the Court restates the allegations, drawn from the Second Amended Complaint and taken as true for purposes of this motion, to the extent necessary to the current motion.

"A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in muscle of connective tissue", typically near the abdominal wall. SAC ¶ 19. One treatment for the condition is hernia repair surgery, during which a surgeon may use hernia mesh constructed from synthetic or biologic materials and tissues to strengthen the repair. Common injuries resulting from surgeries using hernia mesh include "pain, infection, adhesion of scar tissue sticking together, blockages that obstruct intestines, internal bleeding, fistula between organs (abnormal organ connection or fusion), serenoma or fluid buildup at site, and perforation of other organs." SAC ¶ 28.

On February 5, 2015, Dr. Moaz W. Albulfaraj performed a hernia repair surgery on Mrs. Cosh using hernia mesh designed, manufactured, advertised, and sold by Atrium. The specific product, ProLite Mesh, is a mid-weight polypropylene hernia mesh. Approximately six weeks after Mrs. Cosh's surgery, on March 17, 2015, she underwent a second surgery to repair a debridement of a nonhealing wound and remove the mesh, which was infected. Since the surgeries, Mrs. Cosh has experienced stomach pains that were not present prior to the implantation of Defendant's ProLite Mesh.

Plaintiffs allege they have suffered economic damages, physical injuries, emotional distress and mental anguish as a result of Defendant's misrepresentations and omissions

concerning the safety of ProLite Mesh. Specifically, they bring the following claims[1]: Strict Liability Design Defect (Count I), Strict Liability Manufacturing Defect (Count II), Strict Liability Failure to Warn (Count III), Negligence (Count IV), Breach of Warranty (Count V), Punitive Damages (Count VI), Negligent Misrepresentation (Count VIII), Consumer Fraud (Count X), and Loss of Consortium (Count XI).

The Court's February 6, 2020 Opinion dismissed each of the claims. For the reasons below, the Court dismisses them again.

STANDARD OF REVIEW

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When considering a motion to dismiss under Federal Rules of Civil Procedure 12(b)(6), a court should "draw all reasonable inferences in [the plaintiff's] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted). Thus, The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985). The Court should not dismiss the complaint if the plaintiff has stated "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the

[1] Plaintiffs have not repleaded the Amended Complaint's claims for Fraudulent Misrepresentation (Count VII), and Unjust Enrichment (Count IX).

defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Moreover, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Id*. at 663.

DISCUSSION

I. Strict Liability and Negligence Claims

In *Cosh I*, the Court analyzed Plaintiffs' strict liability and negligence claims of design defects, manufacturing defects, and failure to warn together. *Cosh I* at *5. The Court will do so again here.

a. Design Defect

"Under New York law, a plaintiff establishes a prima facie case of products liability for a design defect by showing: (1) that the product, as designed, posed a substantial likelihood of harm; (2) that it was feasible for the manufacturer to design the product in a safer manner; and (3) that the defective design was a substantial factor in causing plaintiffs injury." See *Am. Guar. & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09-CV-8357, 2010 U.S. Dist. LEXIS 137527, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010) (citing *Tuosto v. Philip Morris USA Inc.*, 672 F.Supp.2d 350, 364 (S.D.N.Y. 2009)). "Although a plaintiff need not possess specialized scientific or technical knowledge at the pleading stage, courts have routinely dismissed strict products liability claims premised on a design defect where the plaintiff has failed to plead that it was feasible to design the product in a safer manner ('a feasible alternative design')." *Kennedy v. Covidien, L.P.*, No. 18-CV-01907, 2019 U.S. Dist. LEXIS 54450, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019) (citing *DiBartolo v. Abbott Labs.*, 914 F.Supp.2d 601, 622-23 (S.D.N.Y. 2012)).

In *Cosh I*, the Court concluded that "Plaintiffs [] failed to adequately plead a claim of defective design because they [had] not sufficiently [pleaded] the existence of a feasible alternative design." *Id.* at *6. "Simply asserting that a feasible alternative design exists—without pleading any supporting facts—is not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be." *Id.* (citing *Green v. Covidien LP*, No. 18 CIV. 2939, 2019 WL 4142480, at *3 (S.D.N.Y. Aug. 30, 2019)).

In the Second Amended Complaint, Plaintiffs add several additional allegations relevant to this Count. For instance, Plaintiffs allege that "[e]xperimental studies show that [ProLite] is well incorporated into anterior abdominal wall within two weeks of implantation; however, inflammatory reaction may predispose to adhesion formation and result in contraction of mesh and surrounding tissues". SAC ¶ 55. They also allege that the mesh "is not meant for permanent implantation into the human body or permanent contact with internal body fluids or tissues, and that chemicals migrating out of the plastic (polypropylene) especially when exposed to higher temperatures can make their way into the human body". SAC ¶ 67. Plaintiffs also allege alternative designs that are allegedly less dangerous and equally, if not more effective, than ProLite Mesh: "the use of polycarbonate instead of polypropylene mesh; the use of polystyrene instead of polypropylene mesh; the use of a heavyweight small-pore mesh instead of midweight mesh; [] non-woven mesh instead of a knitted or 'woven' mesh"; or "the use of hemp instead of a synthetic mesh". SAC ¶§¶ 68-69.

The Court concludes these additional allegations do not cure the defects identified in *Cosh I*. Although Plaintiffs allege Defendants could have used heavyweight small-pore mesh instead of midweight mesh or non-woven mesh instead of a knitted or woven mesh, they do not allege facts showing this would be technically and economically feasible and result in a safer

design. Furthermore, as the Court previously indicated, showing that using polycarbonate, polystyrene, or hemp materials would be technically and economically feasible would be insufficient because "alleging that the product should not be used at all is insufficient to satisfy the feasible alternative design element." *Green*, 2019 WL 4142480, at *3 (citing *Kennedy*, 2019 WL 1429979, at *4); *see also Dunham v. Covidien LP*, No. 19 CIV. 2851, 2019 WL 2461806, at *2 (S.D.N.Y. May 22, 2019) (dismissing a similar design defect claim in a hernia mesh products liability case).

Because the additional allegations fail to cure the deficiencies identified in *Cosh I*, the Court dismisses this Count again.

b. Manufacturing Defect

Under New York Law, "to plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *Am. Guar. & Liab. Ins. Co.*, 2010 U.S. Dist. LEX IS 137527, 2010 WL 5480775, at *3 (quoting *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F.Supp.2d 53, 85 (S.D.N.Y.2001)). "Where the plaintiff does not allege a specific flaw in the defective unit, New York law allows the use of circumstantial evidence to establish a manufacturing defect when plaintiff can show that the product did not perform as intended and excludes all other causes for the product failure that are not attributable to the defendant." *Kennedy*, 2019 U.S. Dist. LEXIS 54450, 2019 WL 1429979, at *4 (citing *Goldin v. Smith & Nephew, Inc.*, No. 12-civ-9217, 2013 U.S. Dist. LEXIS 58811, 2013 WL 1759575 *3 (S.D.N.Y. April 24, 2013)).

In *Cosh I*, the Court concluded that Plaintiffs failed to allege a manufacturing defect because they did not identify what specific component of the device was defective or adequately allege any deviations from the manufacturing process, improper workmanship, or defective materials. *Cosh I*, at *8-9. The Court further concluded that Plaintiffs could not use Mrs. Cosh's injuries as circumstantial evidence to establish a manufacturing defect because her injuries are consistent with common injuries and are known side effects caused by hernia repair surgeries using mesh products. *Id.*

In the Second Amended Complaint, Plaintiffs add allegations regarding an FDA Complaint and Warning Letter relating to Atrium's manufacturing facility in Hudson, New Hampshire. The FDA Complaint alleges that during a 2013 inspection, the FDA observed "numerous deviations from regulations for medical devices, including a failure of the company to establish and maintain procedures for implementing corrective and preventive action". SAC ¶ 91. The FDA Complaint cites similar violations during September 2012, March 2010, and March 2009 inspections. A Warning Letter about the same facility from 2012 cited "numerous violations, including violations of the most fundamental safety regulations ensuring sterilization of their devices", such as "35 confirmed instances of hair being found in [Atrium's] sterile medical devices". SAC ¶ 93. That facility was ordered to shut down by a Consent Decree in 2015 and Plaintiffs allege on information and belief that manufacture or distribution of ProLite Mesh has not resumed at the Hudson Facility. SAC ¶ 94. Plaintiffs allege on information and belief that the mesh implanted in Mrs. Cosh was manufactured at the Hudson facility.

These additional allegations to do not cure the deficiencies identified in *Cosh I*. The alleged violations identified in the FDA Complaint, Warning Letter, and Consent Decree do not suffice to plead a deviation from the manufacturing process, improper workmanship, or defective

materials for the *specific* unit of ProLite Mesh implanted in Mrs. Cosh. Moreover, it is not even clear from these documents what the violations were and to what extent they impacted production of ProLite Mesh as compared to other medical devices being manufactured by Atrium. Nor have Plaintiffs pleaded facts showing that the violations alleged might lead to the complications experienced by Mrs. Cosh.

Having concluded that Plaintiffs have not cured the deficiencies identified in *Cosh I*, the Court dismisses this Count.

c. Failure to Warn

In order to recover under a failure to warn theory, a claimant must show: "(1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm." *Am. Guar. & Liab. Ins. Co.*, 2010 U.S. Dist. LEXIS 137527, 2010 WL 5480775, at *3 (quoting *Colon ex rel. Molina*, 199 F. Supp. 2d at 84). As part of satisfying those elements, a plaintiff is "required to prove that the product did not contain adequate warnings." *Mulhall v. Hannafin*, 45 A.D.3d 55, 841 N.Y.S.2d 282, 285 (N.Y. App. Div. 1st Dep't 2007). Generally, whether a warning is adequate is an issue of fact to be determined at trial. *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003) (quoting *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991)).

In *Cosh I*, the Court dismissed Plaintiffs' failure to warn claim because the allegations of inadequate warnings were conclusory. In particular, "Plaintiffs' 'allegations [did] not include any factual content regarding . . . how the provided warnings and information failed to [] accurately reflect[ ] reality' [and did] not provide a plausible basis to support an inference that [Defendant]

misrepresented anything." *Cosh I* at *10 (quoting *Green v. Covidien*, 2019 WL 4142480, at *5 (S.D.N.Y. Aug. 30, 2019)).

In the Second Amended Complaint, Plaintiffs allege that "Atrium represented to Plaintiff and his physicians that ProLite Mesh was a safe and effective product with smooth edges and strong knit construction" and "failed to inform Plaintiff that the ProLite hernia mesh implanted in his body was not made of medical grade polypropylene, that numerous adverse events for this product had been reported to FDA, and that a growing body of medical literature is now warning about the risks of ProLite and similar hernia mesh made of the same type of polypropylene". SAC ¶ 105. It further alleges that "there were no warnings accompanying the sale of the ProLite Mesh explaining that the ProLite Mesh was adulterated; that Atrium failed to follow FDA regulations when it manufactured the product; that Atrium had been cited by the FDA for failing to follow [FDA regulations] in its manufacture of the ProLite Mesh; or that any of the above circumstances would increase the risk of implanting the ProLite Mesh to repair." SAC ¶ 107.

These allegations do not cure the deficiencies identified in *Cosh I*. Though Plaintiffs again indicate that Atrium represented that its product was safe and effective, they still point to no specific statements doing so. The warnings that Plaintiffs allege were not given are merely reframing Plaintiffs' design and manufacturing defect allegations that the Court has already found insufficient. Plaintiffs cannot transmute these insufficient allegations into a failure to warn claim.

Having concluded that the allegations in the SAC do not cure the defects identified in *Cosh I*, this Count is dismissed.

d. *Negligent Misrepresentation*

To state a claim for negligent misrepresentation, a plaintiff must show that: "the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment". *Eaves v. Designs for Fin., Inc.*, 785 F. Supp. 2d 229, 254 (S.D.N.Y. 2011) (quoting *Hydro Investors, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 20 (2d Cir. 2000)). Additionally, "A plaintiff alleging negligent misrepresentation must establish reliance upon a false statement or material misrepresentation or omission, and the learned intermediary rule eliminates the possibility of any such reliance." *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 697 (W.D.N.Y. 2017) (internal citations and quotation marks omitted).

In *Cosh I*, the Court dismissed this claim because Plaintiffs failed to sufficiently allege the Defendant made false representations or on what misrepresentations Mrs. Cosh or her physician relied. *Cosh I*, at *14. In the Second Amended Complaint, Plaintiffs additionally allege that hundreds of adverse events have been reported to the FDA related to failures of ProLite Mesh and Atrium failed to properly investigate them. SAC ¶¶ 134-35. These additional allegations are unrelated to the deficiencies identified in *Cosh I* and clearly do not cure them. Accordingly, this Count is dismissed.

II. Remaining Claims

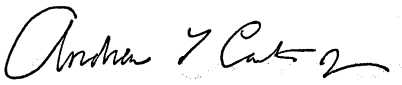
The remaining counts, Consumer Fraud; Punitive Damages; Breach of Warranty; and Loss of Consortium, were dismissed in *Cosh I*. *Cosh I*, at *15-20. The Second Amended Complaint does not plead any additional facts beyond those the Court found deficient in *Cosh I*. Accordingly, the Court dismisses these Counts for the same reasons it did in *Cosh I*.

CONCLUSION

For the foregoing reasons, the Court hereby GRANTS Defendant Atrium's Motion to Dismiss. This case is hereby DISMISSED in its entirety. The Clerk of Court is respectfully directed to close this case.

SO ORDERED.

Dated: March 29, 2021
New York, New York



ANDREW L. CARTER, JR.
United States District Judge